Tissue Medical Lasers, Inc.

OCT 2 7 2000

K000317

Attachment E.

510(k) Premarket Notification - Original submission
Spectra-VRM Q-switched Nd:YAG Laser System
Tissue Medical Lasers, Inc.
January 31, 2000

## 510(k) Summary

| | |
|---|---|
| Submitter: | Tissue Medical Lasers, Inc.<br>4432 Anaheim NE<br>Albuquerque, New Mexico 87113 USA<br>Phone: (505) 828-0508<br>Fax: (505) 828-0525 |
| Contact: | Dwight J. Zurawski |
| Date Summary Prepared: | January 31, 2000 |
| Device Trade Name: | Spectra-VRM Q-switched Nd:YAG Laser System |
| Common Name: | Medical Laser System |
| Classification Name(s): | Instrument, Surgical, Laser powered<br>79-GEX<br>21 CRF 878.4810 |
| Equivalent Device: | Continuum Biomedical Medlite IV Q-Switch Nd:YAG Laser |
| Description of Device: | The active medium in a Nd-YAG laser consists of an yttrium aluminum garnet (YAG) host crystal doped with neodium (Nd) ions. The Nd ions are ultimately responsible for generating laser energy at the wavelengths of medical interest: 1064nm. This Q-switched Nd-YAG laser is flashlamp-pumped device that is electro-optically Q-switched. The flashlamp emits an intense broad-spectrum light that is absorbed by the Nd:YAG crystal that then releases energy as laser light at 1064nm wavelength. |

| | |
|---|---|
| | The Spectra-VRM Q-switched Nd-YAG laser generates pulse energies of several hundred milijoules in a 5-10 nanosecond pulse duration. Pulse rates of 1- 10 pulses per second (Hz) are employed. A frequency doubler is used to change the 1064nm wavelength to 532nm.<br><br>Q-switched Nd-YAG lasers are used for treating a wide variety of dermatological uses including tattoo removal and removal of benign pigmented or vascular lesion of the skin. |
| Intended Use: | 532: Removal of Red Ink Tattoos<br>Removal of Epidermal Pigmented lesions<br>Removal of Minor Vascular Lesions<br>1064: Removal of Black and Blue Ink Tattoos<br>Removal of lightening of unwanted hair |
| Comparison: | The Spectra-VRM Q-switched Nd-YAG laser and the Continuum Biomedical Medlite IV Q-switched Nd-YAG laser are equivalent in operating parameters, physical characteristics and intended uses. The Spectra-VRM laser does not have the dye-impregnated handpieces available that converts the 532nm wavelength to either 585nm or 650nm. Those dye-impregnated handpieces are available with the Continuum Biomedical Medlite IV. |
| Nonclinical Performance Data: | None presented at this time. |
| Clinical Performance Data: | None presented at this time. |
| Additional Information: | None presented at this time. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 7 2000

Mr. Dwight Zurawski
President
Tissue Medical Lasers, Inc.
4432 Anaheim Avenue, N.E.
Albuquerque, New Mexico 87113

Re: K000317
Trade Name: Spectra-VRM Q-switched Nd:YAG Laser System
Regulatory Class: II
Product Code: GEX
Dated: July 28, 2000
Received: July 31, 2000

Dear Mr. Zurawski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000317

Attachment I.

Premarket Notification - 510(k)
Tissue Medical Lasers, Inc.

Statement of Indication for Use

The Spectra-VRM Q-Switched Nd:YAG Laser System is indicated for the following uses:

1. For incision, excision, ablation, vaporization of soft tissue for general dermatology.

2. 532nm wavelength:
   - Removal of light ink (Red, Tan, Purple, and Orange) tattoos
   - Removal of pigmented lesions
   - Removal of vascular lesions
   - Treatment of Lentigines
   - Treatment of Café-Au-Lait
   - Treatment of Common Nevi
   - Treatment of Seborrheic Kratoses
   - Treatment of Post Inflammatory Hyperpigmentation

3. 1064nm wavelength:
   - Removal of dark ink (black, blue and brown) tattoos
   - Treatment of Nevus of Ota
   - Removal or lightening of unwanted hair
   - Treatment of Common Nevi

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000317